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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,344	12/30/2003	Jerome B. Zeldis	9516-070-999 (CAM No.:501	8197

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,344	ZELDIS, JEROME B.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of response to election requirement and remarks filed 05/09/07.

Election/Restrictions

1. Applicant's election without traverse of coated stent having the "JNK" inhibitor *3-(3-(2-(piperidin- 1 -yl)ethoxy)phenyl)-5-(1 H- 1,2,4-triazol-3-yl)- 1H-indazole (*found in the Specification at page 22, second compound) and claims 1-4 and 7-27 in the reply filed on 5/09/07 is acknowledged. Claims 5 and 6 are thus withdrawn from consideration without traverse.

Claim Objections

Claims 1-4, 12, 14 and 15 use the abbreviation/acronym "JNK" to refer to c-Jun-N-terminal kinase ("JNK") Inhibitor without an initial representation of what the abbreviation stands. Applicant may provide initial full meaning of the term in the claim (generic) with parenthetical representation of the abbreviation for subsequent use in dependent claims.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16 and 17 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cardiovascular disease or renal disease atherosclerosis, does not reasonably provide enablement for the prevention of cardiovascular disease or renal disease or atherosclerosis. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is scope of enablement.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)): 1) Nature of invention, 2) State of prior art, 3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure, 4) Level of predictability in the art, 5) Amount of direction and guidance provided by the inventor, 6) Existence of working examples, 7) Breadth of claims, 8) Level of ordinary skill in the art. A representative number of the factors are considered below for prima facie case.

In the instant case, applicants are claiming in part, a method of preventing cardiovascular disease or renal disease or atherosclerosis.

1) Nature of the invention.

The nature of the invention is directed to methods of treating/preventing preventing cardiovascular disease or renal disease or atherosclerosis with a composition/product that is administered after the condition exists. There is no identification for when the administration would take place.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. Further, their mode of action is often unknown or very unpredictable and administration of the drugs can be accompanied by undesirable side effects.

2) State of the prior art and the predictability or lack thereof in the art.

The state of the prior art is that the cardiovascular disease or renal disease or atherosclerosis ate treated after the conditions are identified as being present. There is no cardiovascular condition where the condition is precisely predicted before the onset and where a pharmaceutical composition is administered to prevent its occurrence.

The absence of a showing of correlation between the claimed conditions that are prevented and the composition for treating the conditions show appears to show the unpredictable nature of the preventing thereby imposing undue burden on the artisan to fully predict the process for implementation.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is thus undue experimentation. One of ordinary skill in the art would first need to determine the type of conditions associated with preventing the conditions.

Since the specification fails to provide sufficient support of the broad use of the compounds of the claims for the prevention of the disease conditions, the artisan would have to perform an exhaustive search to determine how the conditions can be prevented and how to practice the claimed invention.

Claim Rejections - 35 USC § 101

Printed Matter Rejection

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

the claimed invention is directed to non-statutory subject matter. **Claim 27 recites directions for its use and applicant is reminded that a** mere arrangement of printed matter, though seemingly a "manufacture," is rejected as not being within the statutory classes. See In re Miller, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); Ex parte Gwinn, 112 USPQ 439 (Bd. App. 1955); and In re Jones, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4 and 7-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al. (US 2002/0103229) in view of Chudzik et al. (US 2002/0188037).

Bhagwat describes method for treating conditions responsive to JNK inhibition by administering pharmaceutical compositions containing any of the compounds and pharmaceutically acceptable carrier (Claim 22; paragraph [0015]). Compounds numbers 243 at para. [1145] and 272 at para. [1320] is the elected compound. Some of the conditions treatable are restenosis following angiolplasty, organ transplantation (para. [0017]) and the product can be implanted (para. [0127]). The carrier meets claims 7. Compound #s 243 and 272 meet the limitations of the JNK inhibitors of the claims. The surgical intervention in angioplasty meets claims 16-26 except that although the composition of the Bhagwat is implanted, there is no specific disclosure for stents. While the compounds of Bhagwat are delivered in a controlled

release of sustained release delivery (para. [0131], [0133] and [0135], Bhagwat is silent on the polymers that lends process to the release profile. However, it is known in the art that polymers such as acrylate polymers are used as sustained release coating carriers. For example, Chudzik discloses acrylate coated stents that provide controlled release of active agents (abstract, para. [0091] and claim 30). Regarding claim 27, compositions are known to be held in containers/kits for ease of handling and a kit is an obvious storage/holding facility for drug compositions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use coated stent for the sustained delivery of compounds 243 and 272 of Bhagwat.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
Tech. Center 1600